

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

**IN RE: JOHNSON & JOHNSON
TALCUM POWDER PRODUCTS
MARKETING, SALES PRACTICES,
AND PRODUCTS LIABILITY
LITIGATION**

MDL No. 16-2738 (MAS) (RLS)

***THIS DOCUMENT RELATES TO ALL
CASES***

**PLAINTIFFS' STEERING COMMITTEE'S MEMORANDUM IN
SUPPORT OF MOTION FOR RECONSIDERATION OF THE
COURT'S MARCH 27, 2024 TEXT ORDER
FOR A FULL REILING OF *DAUBERT* MOTIONS**

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Plaintiffs, by and through the Plaintiffs' Steering Committee ("PSC"), hereby submit this Memorandum in Support of their Motion for Reconsideration of the Court's March 27, 2024 Text Order (ECF No. 30260) that provides for a "full refiling of *Daubert* motions" in this case. The Text Order, unaccompanied by any written opinion providing a legal basis for the decision, is premised on: (1) recent changes to Federal Rule of Evidence 702; (2) emergence of new relevant science; and (3) the language of Chief Judge Wolfson's previous *Daubert* Opinion. None of the aforementioned reasons, either individually or collectively, justify a full refiling of *Daubert* motions, especially where neither party made a request to do so and there was no legal briefing or argument on the issue.

The Text Order is not supported by the record before the Court and is in clear error. The parties should not have to relitigate previously decided issues that are now the law of the case simply because time has passed. The Text Order misinterprets the impact of amendments to Rule 702 and ignores Judge Wolfson's prior findings that were consistent with applicable evidentiary standards and case law. No party appealed Judge Wolfson's April 27, 2020 *Daubert* Opinion, which properly applied the preponderance of evidence standard as required by Rule 702 and its 2023 amendments. There is no sound basis for the Court to order, *sua sponte*, an unprecedented full refiling of *Daubert* motions.

BACKGROUND

I. History Of Litigation and *Daubert* Proceedings

This MDL was created on October 4, 2016, and nearly eight years later the number of pending cases has grown to more than 53,000, all involving plaintiffs suffering or having passed away from ovarian cancer caused by exposure to Defendants' talcum powder products. At the inception of this MDL, Defendants argued that the case should be bifurcated, focusing first on general causation because resolution of that issue would result in dismissal of the case, thereby sparing the parties and the Court costly and lengthy proceedings. Over the PSC's objection the Court determined to proceed in the manner suggested by Defendants. Discovery and *Daubert* proceedings on general causation preceded the selection of any cases for bellwether trials or any discovery on specific causation.

Between the entry of CMO No. 12 in August 2018 (ECF No. 6966), which provided a schedule for general causation expert witnesses and *Daubert* proceedings on general causation, and July 2019, the parties served their respective experts' general causation reports, deposed the general causation experts, and completed *Daubert* briefing on general causation issues. Thousands of pages of *Daubert* briefing and exhibits were submitted to the Court on multiple issues and opinions, including the presence of asbestos, fibrous talc, and heavy metals in the talcum powder products, the contamination of the talcum powder products with

other carcinogens including fibrous talc and heavy metals, biological plausibility, and expert-specific challenges. After *Daubert* briefing was completed, the Court conducted an eight-day *Daubert* hearing between July 22 and July 31, 2019. The hearing culminated in a 141-page decision on April 27, 2020, addressing the parties' dueling *Daubert* motions. (ECF No. 13186). The Court declined to fully exclude the testimony of any of the parties' proffered general causation experts. *Id.* at 140-41. The Court noted: "Importantly, the reasoning in this Court's Opinion applies with equal force to the remainder of the pending [general causation] *Daubert* motions." *Id.* at 2.

Following the *Daubert* rulings, the parties continued with additional discovery, including liability discovery. By the fall of 2021, this MDL was proceeding toward an MDL trial to occur in late spring or early summer of 2022. On July 2, 2021, nearly three years after Plaintiffs' original expert disclosures, Plaintiffs served case-specific expert reports for the six cases in the bellwether pool and amended reports for certain general causation experts. Thereafter, Defendants deposed each of Plaintiffs' experts for which a new or amended report was served. On October 14, 2021, one week prior to the deadline for Defendants to disclose their case-specific and general causation experts, Defendants embarked on their bankruptcy strategy that shielded Defendants from having to disclose and produce reports for their experts. The bankruptcy proceeding was transferred to the District

of New Jersey, and ultimately dismissed on April 4, 2023, pursuant to a decision from the United States Court of Appeals for the Third Circuit. Only a few hours after the first bankruptcy was dismissed, Defendants filed a second bankruptcy in the same bankruptcy court. Following a second trial on a motion to dismiss, the bankruptcy judge dismissed the second bankruptcy on August 11, 2023. The dismissal order is currently on appeal before the Third Circuit.

Defendants' back-to-back bankruptcy filings brought this litigation to a complete standstill for almost two years. Following the dismissal of the second bankruptcy petition, the parties appeared for a Case Management Conference with this Court on September 6, 2023 and discussed several issues, including the status of expert discovery, supplemental and amended expert reports, and the scope of future *Daubert* challenges.

II. The Parties Did Not Request a Full Refiling of *Daubert* Motions in Their Letter Briefs or at the September 6, 2023 Case Management Conference

The Text Order requiring a full refiling of *Daubert* motions goes well beyond anything sought by either party. In advance of the September 6, 2023 Case Management Conference, the parties submitted competing letters limited to the issue of how language related to *Daubert* should be stated in an otherwise agreed upon Case Management Order. In their August 23, 2023 letter to the Court, Defendants stated that “Defendants have not decided how they will proceed in the future with regard to such opinions they will challenge, but they ask that a

scheduling order not handcuff them and prevent them from raising *Daubert* arguments to the Court.”¹ At the September 6, 2023 Case Management Conference, Defendants further clarified that they were not seeking a total refiling of *Daubert* but, instead, would focus *Daubert* challenges on case-specific and only certain other issues. See Transcript of Sept. 6, 2023 Case Management Conference at 16:17-22 (“And then when we make our Rule 702 challenges *on specific causation and other issues*, if the plaintiffs think that we are not following what Chief Judge Wolfson would have done based on 2019 science and 2020 law, they can raise that in their opposition, we can respond, and you can rule on that.” (emphasis added)); 17:17-24 (“When one looks at Judge Wolson’s opinion, she used the word ‘weight’ 55 times. Now, am I going to reargue each of those 55 things? I don’t think so. But I’d like to have the opportunity depending on the facts, depending on the circumstances, depending on the expert’s opinion. So that is all we are asking, that we leave it open and we deal with it when the moment arises.”).²

The decision of the Court to undertake a full refiling of *Daubert* is unprecedented, not supported by the record, and is in clear error.

¹ Defendants’ August 23, 2023 letter is attached hereto as **Exhibit A**.

² Excerpts of the transcript from the September 6, 2023 Case Management Conference are attached hereto as **Exhibit B**.

LEGAL ARGUMENT

I. Legal Standards On Motion For Reconsideration

A timely motion for reconsideration requires a finding of at least one of the following factors: (1) an intervening change in the controlling law; (2) the availability of new evidence that was not available when the application at issue was decided; or (3) the need to correct a clear error of law or fact or to prevent manifest injustice. *In re Vehicle Carrier Servs. Antitrust Litig.*, 846 F.3d 71, 87 (3d Cir. 2017), *as amended* (Jan. 25, 2017); *Max's Seafood Cafe ex rel. Lou-Ann, Inc. v. Quinteros*, 176 F.3d 669, 677 (3d Cir. 1999). Movants must identify the matters which they believe the Judge overlooked in the ruling. Local Rule 7.1(i). "A court commits clear error of law only if the record cannot support the findings that led to the ruling." *Rich v. State*, 294 F. Supp. 3d 266, 272 (D.N.J. 2018) (internal quotation marks omitted); *United States v. Grape*, 549 F.3d 591, 603–04 (3d Cir. 2008). The movant must do more than allege that portions of the ruling were erroneous and mere disagreement with the ruling does not suffice; the movant must demonstrate that (1) the court's holdings were without support in the record, or (2) the court's holdings would result in manifest injustice if not addressed. *Grape*, 549 F.3d at 603–04.

II. The Court’s Decision Ordering A Full Refiling Of *Daubert* Is Not Supported By The Record And Would Be Manifestly Unjust

The Court’s Text Order calling for a full refiling of *Daubert* motions rests on three unsupported bases: (1) recent changes to the Federal Rule of Evidence 702; (2) the language of Chief Judge Wolfson’s previous *Daubert* Opinion; and (3) changes to the relevant science. However, the record does not support any of these bases, either individually or collectively, for a full refiling of *Daubert* motions, and it would therefore be manifestly unjust to require the parties to once again expend substantial time and resources fully re-litigating *Daubert*. This is particularly true given the two years already lost to the MDL plaintiffs while Defendants’ bad-faith bankruptcy cases were pending.

A. Amendments to Rule 702 do not support reopening *Daubert*

The Advisory Committee Notes related to the 2023 amendments to Rule 702 make clear that the amendments were *not* intended to change the law. Instead, the Rule was amended “to *clarify and emphasize* that expert testimony may not be admitted unless the proponent demonstrates to the court that it is more likely than not that the proffered testimony meets the admissibility requirements set forth in the Rule.” Adv. Com. Notes to Rule 702 (2023) (emphasis added). The preponderance standard has been an undeniable part of Rule 702 for more than twenty years since the Advisory Committee amended Rule 702 “in response to” the Supreme Court’s opinion in *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S.

579 (1993), and the many cases applying it. The 2000 Advisory Committee Note introduced the concept that “the proponent has the burden of establishing that the pertinent admissibility requirements are met by a preponderance of the evidence” into Rule 702. *See* Adv. Com. Notes to Rule 702 (2000).

“The Committee concluded that emphasizing the preponderance standard in Rule 702 specifically was made necessary by the courts that have failed to apply correctly the reliability requirements of that rule.” Adv. Com. Notes to Rule 702 (2023). *See also Allen v. Foxway Transp., Inc.* No. 4:21-CV-00156, 2024 WL 388133, at *3 (M.D. Pa. Feb. 1, 2024) (holding the recent amendments were “motivated by the Advisory Committee’s ‘observation that in a number of federal cases ... judges did not apply the preponderance standard of admissibility to Rule 702’s requirements,’” which was an incorrect application of Rule 702); *S.Y. v. Roman Cath. Diocese*, Case No. 20cv2605 EP CLW, 2024 WL 123133, at *2 n.9 (D.N.J. Mar. 21, 2024) (recognizing same). “***Nothing in the amendment imposes any new, specific procedures***. Rather, the amendment is simply intended to clarify that Rule 104(a)’s requirement applies to expert opinions under Rule 702.” Adv. Com. Notes to Rule 702 (2023) (emphasis added).

The Advisory Committee Notes are significant because, as compared to ***changing*** the law as Defendants erroneously stated in their August 23, 2023 letter

to the Court,³ the amendments to Rule 702 *clarified* the law that was already in place. The 2023 amendments to Rule 702 are not intended to provide a *carte blanche* opportunity to redo prior proceedings. The Court overlooked that the Advisory Committee Notes make clear the recent amendments to Rule 702 did not *change* the *Daubert* standards and a Text Order directing the full refiling of *Daubert* motions premised on a change to the Federal Rule of Evidence 702 is in clear error and not supported by the record because, as the Advisory Committee Notes make clear, there were not changes to the preponderance standards of Rule 702.

B. Judge Wolfson’s April 27, 2020 *Daubert* Opinion is the law of the case

“Under the doctrine of the law of the case, a decision on an issue made by a court at one stage of a case should be given effect in successive stages of the same litigation. *United States v. Todd*, 920 F.2d 399, 403 (6th Cir. 1990). *See also Tice v. Amer. Airlines, Inc.*, 373 F.3d 851, 853 (7th Cir. 2004). There is no evidence before the Court that Judge Wolfson failed to appropriately preside over the *Daubert* proceedings in this case or, more importantly, that the Court’s *Daubert* rulings were in error. To the contrary, the parties had ample opportunity to appeal the Court’s *Daubert* rulings if there were suspected errors, but the parties chose not

³ See Exhibit A at 3.

to do so. In fact, following entry of the Court's *Daubert* Opinion, a subsequent Letter Order was entered by the Court on June 24, 2020 (ECF No. 13715).⁴ The Letter Order stated that "the parties appear to agree that the Court's rulings with respect to epidemiology and the Bradford Hill analyses are binding on all experts who offer such opinions. The parties further agree that the Court's rulings with respect to Dr. Longo's testimony will be binding on Dr. Rigler." Letter Order at 2. The only unresolved issues related to those experts for whom the Court had not ruled on the motions to exclude. *Id.* No parties raised issue with the Court's findings in general, or that the Court had failed to apply the preponderance standard, in particular. Issue cannot be raised now where there were: (1) no appeals of the decision at the time it was entered; and (2) no change in the statutory requirements or case law at any time since entry of the Opinion.

"The law of the case doctrine does not limit the power of trial judges to reconsider their prior decisions, but have noted that when a court does so, it must explain on the record why it is doing so and take appropriate steps so that the parties are not prejudiced by reliance on the prior ruling." *Pub. Int. Rsch. Grp. of N.J., Inc. v. Magnesium Elektron. Inc.*, 123 F.3d 111, 117 (3d Cir. 1997). *See also Williams v. Runyon*, 130 F.3d 568, 573 (3d Cir. 1997) (same). The record does not support a full refiling of *Daubert* motions but, to the extent the Court seeks to redo *Daubert*,

⁴ A copy of the June 24, 2020 Letter Order is attached hereto as **Exhibit C**.

the parties are severely prejudiced by the absence of an explanation on the record as to the bases for the decision.

C. Judge Wolfson properly applied a preponderance standard to *Daubert*

Judge Wolfson’s Opinion demonstrates that she had a full understanding of her role overseeing *Daubert* and was fully versed in Rule 702 and the law governing the *Daubert* analysis. The 141-page opinion painstakingly reviewed the governing law and the Court’s role as a gatekeeper of admissible evidence. At the outset of the *Daubert* Opinion, Judge Wolfson stated:

It is well-established that “Rule 702 embodies a trilogy of restrictions on expert testimony: qualification, reliability, and fit.” *Ruggiero v. Yamaha Motor Corp., U.S.A.*, 778 F. App’x 88, 93 (3d Cir. 2019) (quoting *Schneider ex rel. Estate of Schneider v. Fried*, 320 F.2d 396, 404 (3d Cir. 2003)). In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the Supreme Court defined the operation and scope of Rule 702 with respect to expert testimony. The *Daubert* Court ruled that trial courts must perform a gatekeeping function to ensure the relevance and reliability of expert testimony. *Id.* at 589–95. In conducting this analysis, courts are to consider “all aspects of the expert’s testing: the methodology, the facts underlying the expert’s opinion, [and] the link between the facts and the conclusion.” *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 291–92 (3d Cir. 2012) (alteration in original) (quoting *Heller v. Shaw Indus., Inc.*, 167 F.3d 146, 155 (3d Cir. 1999)). Moreover, courts must ensure that expert testimony reflects accepted standards within the relevant scientific and business communities. *See In re Johnson & Johnson Derivative Litig.*, 900 F. Supp. 2d 467, 492 (D.N.J. 2012) (“[T]he Court’s role under Rule 702 is to ensure that expert testimony reflects accepted standards within the relevant scientific and business communities—it is not to serve as an umpire between competing subsets of a given community.”).

In re Johnson & Johnson Talcum Powder Prod. Mktg., Sales Pracs. & Prod. Litig.,

509 F. Supp. 3d 116, 130–31 (D.N.J. 2020).

In entering her Order and Opinion, Judge Wolfson held true to the requirements of *Daubert* and Rule 702. The Court properly applied the preponderance standard as required by Rule 702, referencing on multiple occasions that admissibility had to be established by a preponderance of the evidence. *See In re Johnson & Johnson Talcum Powder Prod. Mktg., Sales Pracs. & Prod. Litig.*, 509 F. Supp. 3d at 147–48 (finding that Plaintiffs met their burden as to Dr. Longo and citing to case law establishing that the Court was aware that “[t]he proponent bears the burden of establishing admissibility by a preponderance of the evidence.” (emphasis added)). *See also id.* at 187 (citing *In re Processed Egg Prods. Antitrust Litig.*, 81 F. Supp. 3d 412, 416 (E.D. Pa. 2015) (“Proponents of expert testimony do not ‘have to prove their case twice—they do not have to demonstrate to the judge by a preponderance of the evidence that the assessments of their experts are correct, they only *have to demonstrate by a preponderance of evidence that their opinions are reliable.*’” (citation omitted) (emphasis added))).

Nowhere in Judge Wolfson’s *Daubert* Opinion did the Court indicate that any standard other than a preponderance standard was appropriate for testing the admissibility of expert evidence. Just because the Opinion does not state at every turn that there is a preponderance standard does not mean that the court was not applying it. To the extent such an error did occur, the time for a party to raise issue

with such an error on appeal has long passed. It is clear error on the part of this Court to order a full refiling of *Daubert* based upon the language of Chief Judge Wolfson's previous *Daubert* Opinion, especially since Judge Wolfson made clear in the record that the preponderance standard that was applied.

D. Recently published studies do not change the experts' methodology or Judge Wolfson's findings

There is nothing in the record to support a full refiling of *Daubert* motions. Tellingly, the recent Rule 702 Advisory Committee Notes state that "the fact that the expert has not read every single study that exists will raise a question of weight and not admissibility." Adv. Com. Notes to Rule 702 (2023). Courts have previously denied parties' requests to fully revisit prior *Daubert* rulings simply because new studies were published. *See, e.g., In re Gadolinium-based Contrast Agents Prods. Liab. Litig.*, 2013 WL 587655, at *11 (N.D. Ohio Feb. 13, 2013) (holding that if the "science had changed... [the party] could propose a supplemental expert report based upon that new science," but could only address materials that were not available to the expert at the time of the original report).

Following Judge Wolfson's 2020 *Daubert* decision, only a handful of papers with new analyses have been published. As the PSC previously noted to the Court, the recently published literature was considered by Plaintiffs' experts and

incorporated into their amended reports served on November 15, 2023.⁵ These studies do not change the sound methodologies employed by Plaintiffs' experts and found acceptable by Judge Wolfson, but do affirm and strengthen the opinions of the experts that genital exposure of talcum powder can cause ovarian cancer. For example, O'Brien, et al. published a pooled study in the Journal of American Medical Association in 2020.⁶ The O'Brien investigators pooled data from the three (3) cohort studies: Nurse's Health Study I and II (NHS), Women's Health Initiative (WHI), and the Sisters' Study. The O'Brien study included 252,745 subjects with a total of 1,884 medically confirmed ovarian cancers. Notably, O'Brien found there was a significantly elevated risk in women with **patent (open) reproductive tracts** (RR 1.13; CI 1.01-1.26). In addition, a statistically significant increased risk was noted in **frequent users** (at least weekly).

Historically, systematic reviews of talcum powder use and ovarian cancer focused on "ever use," a non-specific exposure which can obscure meaningful associations. As recently as 2022, Drs. Woolen, Lazar, and Smith-Bindman⁷

⁵ The PSC's November 27, 2023 letter is attached hereto as **Exhibit D**.

⁶ O'Brien et al., *Association of Powder Use in the Genital Area with Risk of Ovarian Cancer*. 323 JAMA 49 (2020); O'Brien et al., *Supplementary Online Content* (2020).

⁷ Dr. Rebecca Smith-Bindman is an epidemiologist and serves as a general causation expert for the PSC in this litigation.

conducted a systematic review and meta-analysis of observational studies to estimate the association between frequent (at least 2 times per week) genital talcum powder use and ovarian cancer.⁸ This review reported that frequent talcum powder use was associated with a statistically significant **47% increased** risk of ovarian cancer.

Irrespective of whether the recent publications are qualitatively better for plaintiffs or better for defendants, it is clear that the articles do not change or undermine the methodologic foundation of Judge Wolfson's *Daubert* opinion.

What Judge Wolfson concluded at the time of her *Daubert* ruling remains true today:

Ultimately, the question of whose experts are correct is a question for the jury; it would be erroneous for this Court to make those factual findings on a *Daubert* motion.

In re Johnson & Johnson Talcum Powder Prod. Mktg., Sales Pracs. & Prod. Litig., 509 F. Supp. 3d at 118.

It is clear error for the Court to order a full refiling of *Daubert* motions based upon an “emergence of new relevant science” when, in fact, the science is not new. Instead, researchers continue to evaluate the existing science and publish based upon those evaluations.

⁸ Woolen, SA, et al., *Association Between the Frequent Use of Perineal Talcum Powder Products and Ovarian Cancer: a Systematic Review and Meta-analysis*, J. Gen. Intern. Med. (2022).

E. Case law does not support a decision to refile *Daubert*

Since December 2023 when the amendments to Rule 702 became effective, several courts have addressed the question of whether the amendments require either a refile of prior *Daubert* proceedings or a change in the applicable *Daubert* standards. Courts considering the issue have held there is no need to revisit prior *Daubert* proceedings or to engage in a different manner of handling *Daubert*. For example, in *In re: Social Media Adolescent Addiction/Personal Injury Prods. Liab. Litig.*, No. C 22-MD-03047-YGR, MDL No. 3047, Judge Yvonne Gonzalez Rogers discussed what impact, if any, the amendments to Rule 702 imposed. Judge Roberts stated that the amendments did not result in any substantive changes:

THE COURT: In terms of you say the new Rule 702, 702 was amended to make it clear to district judges what the rule actually is.

MR. SCHMIDT: Yes.

THE COURT: And was. Substantively it hasn't changed.

MR. SCHMIDT: Yes.

THE COURT: It was encouraging us to do more.

I have to say that in this district our judges were doing it anyway.

MR. SCHMIDT: Yes.

THE COURT: And so I don't think in my view it's changed.

See Excerpts of January 26, 2024 Transcript of Proceedings in *In re: Social Media* at 32:1-32:22.⁹

Similarly, in *In re: Bair Hugger Forced Air Warming Devices Prods. Liab. Litig.*, No. 15-2666-JNE-DTS, the court denied a request by Defendants to renew motions to exclude plaintiffs’ general causation medical experts premised on amendments to Rule 702. The Bair Hugger defendants, in addition to arguing “[t]he amendments to Rule 702 changed the law” also argued “[t]he science in the intervening years also justifies revisiting general causation.” See January 9, 2024 letter brief in *In re: Bair Hugger*, 15-md-02666-JNE-DTS, Dkt. No. 2387, at 1.¹⁰ In a Text Order, the *Bair Hugger* court denied defendants’ request for leave to file a renewed motion to exclude Plaintiffs’ general causation medical experts. See *In re: Bair Hugger* Text Order, Dkt. No. 2393.¹¹ See also *Mills v. City of Philadelphia*, No. CV 14-593, 2024 WL 1253688, at *2 n.5 (E.D. Pa. Mar. 22, 2024) (holding that amendments to Rule 702 do not change existing law but, instead, simply clarify the correct standards to be applied); *Thomas v. State Farm*

⁹ A copy of excerpts of the January 26, 2024 *In re: Social Media* transcript are attached hereto as **Exhibit E**.

¹⁰ A copy of the *Bair Hugger* defendants’ January 9, 2024 Letter is attached hereto as **Exhibit F**.

¹¹ A copy of the January 30, 2024 *Bair Hugger* Text Order is attached hereto as **Exhibit G**.

Mut. Auto. Ins. Co., No. 4:22-CV-724 RLW, 2024 WL 195752, *2 n.1 (E.D. Mo. Jan. 18, 2024) (recognizing that “[t]he Court’s decision regarding the admissibility of Plaintiff’s expert would be the same under either version of the Rule.”).

CONCLUSION

The March 27, 2024 Text Order calling for a full refiling of *Daubert* motions is clearly erroneous and not supported by the record. Requiring a full refiling of *Daubert* motions would also result in manifest injustice to the parties given the extraordinary amount of time and resources required to relitigate the same issues again. At most, the record supports a finding that *Daubert* hearings on newly designated experts or, possibly, limited *Daubert* hearings on discrete issues disclosed in supplemental and/or amended reports may be warranted.

Dated: April 4, 2024

Respectfully submitted,

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